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Registration Decision

RD2010-04

***Bacillus subtilis* strain MBI 600 Integral™ Liquid Biological Fungicide**

(publié aussi en français)

13 April 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

HC Pub: 100161

ISBN: 978-1-100-15556-2 978-1-100-15557-9

Catalogue number: H113-25/2010-4E H113-25/2010-4E-PDF

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Registration Decision for *Bacillus subtilis* strain MBI 600 Integral™ Liquid Biological Fungicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide, containing the technical grade active ingredient *Bacillus subtilis* strain MBI 600, for use as a seed treatment to suppress the seedling disease complex in canola (seed rot, pre and post emergent damping-off, seedling blight and root rot) caused by *Rhizoctonia* spp. and *Fusarium* spp.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹: Proposed Registration Decision PRD2009-17 — *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide. This Registration Decision² describes this stage of the PMRA's regulatory process for *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-17. This decision is consistent with the proposed registration decision stated in PRD2009-17.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-17 - *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide?

Bacillus subtilis strain MBI600 is a microbial pest control product that is antagonistic to fungal pathogens that cause seedling diseases caused by *Rhizoctonia* and *Fusarium* in canola. The protective effect of *Bacillus subtilis* is primarily attributed to competitive exclusion of pathogenic organisms. The end-use product Integral™ Liquid Biological Fungicide is a liquid seed treatment that contains *Bacillus subtilis* strain MBI600. It is to be used primarily in combination with a conventional canola seed treatment fungicide.

Health Considerations

Can Approved Uses of *Bacillus subtilis* strain MBI 600 and Integral™ Liquid Biological Fungicide Affect Human Health?

***Bacillus subtilis* strain MBI 600 is unlikely to affect your health when Integral™ Liquid Biological Fungicide is used according to the label directions.**

People could be exposed to *B. subtilis* strain MBI 600 when handling and applying the product. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g., production of toxic by-products), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses for the purpose of identifying any potential pathogenicity, infectivity and toxicity concerns. When *B. subtilis* MBI 600 was tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the Pest Control Products Act (PCPA) for the purposes of the adulteration provision of the Food and Drugs Act (FDA). Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

Strains of *B. subtilis* are common in nature and the use of Integral™ Liquid Biological Fungicide as a seed treatment to control fungal disease in crops is not expected to significantly increase natural environmental background levels of this microorganism. Few, if any, bacteria are expected to remain as residues on plants at harvest because *B. subtilis* strain MBI 600 is applied as a seed treatment to canola seeds. Some strains of *B. subtilis* have been isolated from food samples implicated in food poisoning; however, these strains demonstrated the ability to produce a highly heat-stable toxin that may be similar to a toxin produced by *Bacillus cereus*, a known food-borne pathogenic microorganism. *Bacillus subtilis* strain MBI 600 is not reported to produce this toxin. Also, no such effects were reported for this microorganism in the United States where it has been registered since 1994. Furthermore, when *B. subtilis* strain MBI 600 was administered orally to rats, no signs that it caused toxicity or disease were observed.

The establishment of a MRL is therefore not required for *B. subtilis* strain MBI 600. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risks are minimal to non-existent.

Occupational Risks From Handling Integral™ Liquid Biological Fungicide

Occupational risks are not of concern when Integral™ Liquid Biological Fungicide is used according to label directions, which include protective measures

Workers using Integral™ Liquid Biological Fungicide can come into direct contact with *B. subtilis* strain MBI 600 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that workers exposed to Integral™ Liquid Biological Fungicide, must wear gloves, long-sleeved shirts, long pants, and shoes plus socks. Furthermore applicators, mixers, and loaders of Integral™ Liquid Biological Fungicide will be required to wear a NIOSH approved respirator (with any N, P, R or HE filter).

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When IntegralTM Liquid Biological Fungicide Is Introduced Into the Environment?

Environmental risks are not of concern

Information on the environmental fate of *Bacillus subtilis* strain MBI 600 suggests that, as a soil microorganism, it is likely that *B. subtilis* strain MBI 600 could survive in outdoor soil under suitable environmental conditions (i.e., type of soil, moisture, acidity levels, and temperature) but that over time the populations of *B. subtilis* strain MBI 600 should return to naturally occurring levels.

In published literature, other strains of *B. subtilis* have been reported to cause infections in mammals, terrestrial insects and plants. However, these reports were few in number considering the large amount of published literature on this microorganism. Furthermore, these reports involved either unusual strains, or select strains, of *B. subtilis*, for which their ability to cause disease was not thoroughly investigated. There are no published reports of disease associated with *B. subtilis* strain MBI 600 in birds, earthworms, bees, aquatic invertebrates, fish, algae, and aquatic plants, except for the intended pest. Furthermore, studies designed to examine the effects of *B. subtilis* to birds, wild mammals, terrestrial insects, earthworms, soil microorganisms reported no adverse effects.

Value Considerations

What Is the Value of IntegralTM Liquid Biological Fungicide?

IntegralTM Liquid Biological Fungicide is a reduced-risk biofungicide that provides suppression of seed rot, pre and post emergent damping off, seedling blight and root rot in canola seedlings when used alone. Control of these diseases is achieved when IntegralTM Liquid Biological Fungicide is used in combination with Helix Liquid Seed Treatment, Helix XTra Seed Treatment or Prosper FL Flowable Insecticide and Fungicide Seed Treatment.

IntegralTM Liquid Biological Fungicide has been shown to provide an increase of about five to ten percent in final plant stands in canola fields when applied as a stand-alone seed treatment or in combination with other conventional seed treatments commonly used by seed companies in Canada. Because of the microbial nature of its active ingredient, seedling disease suppression of IntegralTM Liquid Biological Fungicide is likely to persist late into the seedling development stages. IntegralTM Liquid Biological Fungicide is the first biological fungicide being registered for use as a canola seed treatment in Canada.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Integral™ Liquid Biological Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because of concerns with users developing allergic reactions through repeated high exposures to *B. subtilis* strain MBI 600, anyone formulating, handling, mixing/loading, applying or involved in clean-up/repair activities of Integral™ Liquid Biological Fungicide must wear waterproof gloves, a long-sleeved shirt, long pants, and a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any N-95, R-95, P-95 or HE filter.

Environment

As a general precaution, label statements will be added to the label requiring handlers to not contaminate irrigation or drinking water or aquatic habitats by cleaning of equipment or disposal of wastes.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).
2. Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website under Request a Reconsideration of Decision (www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

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PMRA 1762433	2009, <i>Bacillus subtilis</i> strain MBI600 Preservation and Long Term Storage at Nottingham University School of Agriculture, DACO: M2.7.1,M2.8
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